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(71) Applicant *(for all designated States except US)*: CARDIAC MARINERS INCORPORATED [US/US]; Suite 4, 401 Alberto Way, Los Gatos, CA 95032 (US).

(71) Applicant *(for US only)*: WILENT, Virginia (heiress of the deceased inventor) [US/US]; 139 Victoria Lane, Aptos, CA 95003 (US).

(72) Inventor: WILENT, John, William (deceased).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: MOORMAN, Jack, Wilson [US/US]; 136 Pinta Court, Los Gatos, CA 95032 (US).

(74) Agents: RITCHIE, David, B. et al.; 2099 Lincoln Avenue, Suite 101, San Jose, CA 95125 (US).

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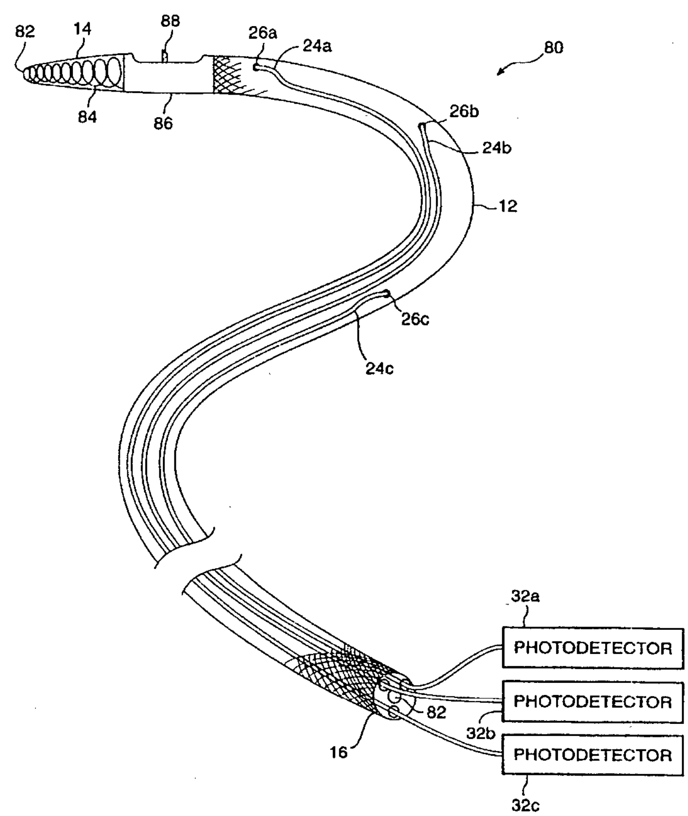
(57) Abstract

A catheter (10) comprises an elongated body (12) having a distal end (14) adapted to be inserted into a body cavity, vessel, tract, or the like and a proximate end (16) available to a person performing a medical procedure. The catheter (10) includes at least one lumen (18) running therethrough. An optical fiber (24) is disposed in the at least one lumen (18) and extends from the distal end (14) to the proximate (16) thereof. An x-ray sensitive phosphor material (26) is disposed at the tip (28) of the end of the optical fiber (24) positioned at the distal end (14) of the catheter (10) and the end (28) of the optical fiber at the proximate end (16) of the catheter (10) is coupled to a photodetector (32).



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SPECIFICATION

CATHETER INCLUDING AN X-RAY SENSITIVE OPTICAL-SENSOR LOCATING DEVICE

BACKGROUND OF THE INVENTION

1. TECHNICAL FIELD

The present invention generally relates to identifying the unique location of a marker transported in a maneuverable positioner by use of an x-ray system. More particularly, the present invention relates to devices incorporating such a marker such as a medical catheter which includes an x-ray sensitive optical sensor locating device, useful in diagnostic or therapeutic x-ray procedures in conjunction with scanning beam x-ray apparatus .

2. BACKGROUND ART

In numerous fields of application, including medical and industrial, it is desirable to discern the location of internal features of an object. In some of these applications, insertion of an x-ray sensitive device is feasible. Industrial fields are variously called x-ray inspection, x-ray analysis, failure analysis, and in-situ testing. In the medical field, examples include, but are not limited to, interventional cardiology, interventional electrophysiology,interventional radiology and interventional neurology.

For example, until 1982 the field of electrophysiology was a small subspecialty of cardiology. Physicians in this field performed studies of the electrical function of the heart. Based on their studies, referring physicians might perform open chest surgery, prescribe antiarrhythmic drugs, or take no therapeutic

action. These studies were carried out using intracardiac electrodes mounted on catheters and with surface electrodes. The intracardiac electrodes could not only measure cardiac action potentials but could also provide stimulation to pace the heartbeat.

Since 1982 there has been increasing use of catheter ablation to cure certain types of arrhythmia. In these types of arrhythmia, such as Wolff-Parkinson-White syndrome, the conductive congenital muscle fibers can be made nonconductive by heating them locally to a sufficient temperature to cause scar tissue to form. Most of these ablations are done with radio-frequency energy but the emitting electrode must be placed within one to three millimeters of the fiber location and it must stay in intimate contact for a number of heartbeats and respiratory cycles.

In 1989 a study of certain antiarrhythmic drugs was prematurely terminated due to a higher mortality for patients taking the drugs than the controls. These findings have caused increased conservatism prescribing drugs and has increased the interest and use of catheter ablation. With the advent of the automatic implantable Cardioverter Defibrillator (AICD), electrophysiologists have taken a lead role in performing the studies which must be performed prior to their implantation.

Although the treatment of arrhythmia through catheter ablation has some advantages, there are also some problems. The advantages are a very high success rate, the procedure is minimally invasive, can be performed in a few hours in a procedure room, and is considerably less expensive than open chest surgery

or a lifetime of drugs. The major disadvantages are that the length of the procedure is both uncertain and typically long. This leads to higher costs, inability to schedule physicians and facilities, fatigue for both patient and staff, and high radiation dosages.

Attempts to solve these problems have focused mainly on providing more steerable catheters to reduce the time to find the precise location of the ablation site and to position the catheter for remaining in contact with the substrate during the ablation time, which is typically five to ninety seconds for each "buzz". Having more steerable catheters has not yet reduced the time or uncertainty of time because the location of the catheter can only be generally determined by looking at an x-ray projected on a monitor and by analyzing the electrocardiogram. Both of these actions must be done in real time in order to know whether to move the catheter and in which direction to move it. The actual direction of movement is uncertain due to the nature of an x-ray image of soft tissue and blood, the poor control and feedback of the catheter, the movement of the heart, and the difficulty of determining direction from the electrocardiogram analysis.

In the U.S., there are currently 300,000 to 500,000 people who die each year due to arrhythmia that is a result of a myocardial infarction. There is no cure for the problem. However, it is believed that if the slow conduction zone around the infarct could be electrically mapped and selectively ablated, that the cure would be obtained. Tests on animals and some humans have demonstrated the possibility of such a procedure but the success rate has been low. The reason for the low success is thought to be the need to map the entire area of the infarct and slow conduction zone and then to be able to ablate multiple sites without depending on

acquiring a characteristic electrogram once the ablation has begun. There are current investigations attempting to solve the problem utilizing a network of nodes but this has the problem of extracting the nodal network array from inside the heart without damaging the heart.

It is therefore one object of the present invention to provide a catheter whose position may be accurately determined during a medical diagnostic or therapeutic procedure.

DISCLOSURE OF INVENTION

The present invention relates to a marker transported in a maneuverable positioner which allows identification of its unique location by use of an x-ray system. In its most general sense, the present invention comprises an x-ray sensitive marker material disposed in a body and includes means for transmitting an indication of the presence of x-ray radiation outside of the body in which it is disposed. As presently preferred, the marker material is a scintillating crystal or phosphor material optically coupled to one end of an optical fiber which extends beyond the boundaries of the body. The other end of the optical fiber may be optically coupled to a photodetector. Alternatively, the marker may comprise a transducer for converting x-ray radiation to an electrical signal and may be electrically coupled to a wire or wires which are used to transmit the electrical signal beyond the boundaries of the body in which it is contained.

According to one embodiment of the invention useful in medical applications, a catheter comprises an elongated body having a distal end adapted to be inserted into a bodily cavity, vessel, tract, or the like and a proximate end

available to a person performing a medical procedure. The catheter includes at least one lumen running therethrough. An optical fiber is disposed in the at least one lumen and extends from the distal end to the proximate thereof. An x-ray sensitive phosphor material is disposed at the tip of the end of the optical fiber positioned at the distal end of the catheter and the end of the optical fiber at the proximate end of the catheter is coupled to a photodetector.

The principles of the present invention may be employed in any application, medical or industrial, where location of internal features of an object is desired and insertion of an x-ray sensitive device is feasible. Industrial fields are variously called x-ray inspection, x-ray analysis, failure analysis, and in-situ testing.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG 1 is a diagram of a catheter according to a presently preferred embodiment of the present invention.

FIG. 2 is a cross-sectional view of the catheter of FIG. 1.

FIG. 3 is a detailed view of the distal end of the catheter of FIGS. 1 and 2.

FIG. 4a is a diagram of an electrophysiology catheter employing the present invention.

FIG. 4b is a diagram of a balloon angioplasty catheter employing the present invention.

FIG. 4c is a diagram of an atherocatheter employing the present invention.

FIG. 4d is a diagram showing how the x-ray markers of the present invention may be used to determine the rotational orientation of the catheter in which they are employed

FIG. 5 is a block diagram illustrating an application of the present invention with a digital scanning beam x-ray system.

FIG. 6 is a block diagram similar to that of FIG. 5, illustrating an application of the present invention with two digital scanning beam x-ray systems for locating the marker in three dimensions.

MODES FOR CARRYING OUT THE INVENTION

Those of ordinary skill in the art will realize that the following description of the present invention is illustrative only and not in any way limiting. Other embodiments of the invention will readily suggest themselves to such skilled persons. While the preferred embodiment of the invention contained herein is disclosed in the context of medical catheters specifically as applied to catheter ablation of cardiac arrhythmias, those of ordinary skill in the art will readily recognize that the present invention is generally and broadly applicable to x-ray markers disposed in positionable bodies.

Referring first to FIGS. 1 and 2, diagrams are presented of a catheter 10 according to a presently preferred embodiment of the invention. As shown in FIG. 1 and as will be appreciated by those of ordinary skill in the art, catheter 10 is an

elongated body which may be formed from a variety of materials, such as plastic and steel. Catheter 10 comprises an elongated body 12 having a distal end 14 adapted to be inserted into a bodily cavity, vessel, tract, or the like and a proximate end 16 available to a person performing a medical procedure.

Referring particularly to FIG. 2, catheter 10 is shown to include a plurality of lumens 18, 20, and 22. While the catheter 10 is shown including three lumens 18, 20, and 22, those of ordinary skill in the art will readily recognize that this embodiment is merely illustrative to point out the features of the invention and that the number of lumens provided in any actual catheter fabricated according to the present invention and the uses therefore will depend solely on the end use to which catheter 10 will be put. Such a catheter may be steerable to be positioned by manipulation as is known in the art.

Referring again to FIG. 1, an optical fiber 24 is disposed in lumen 18 of catheter 10. For small diameter catheters, such as ones used in cardiac applications, optical fiber 24 may have a diameter of approximately 0.025-0.051 cm (0.010-0.020 inch. Those of ordinary skill in the art will of course recognize that optical fiber 24 may have other diameters without departing from the scope of the present invention. An x-ray marker 26, preferably comprising an sensitive phosphor material or crystal, is optically coupled to a distal end 28 of the optical fiber 24. X-ray marker material 26 may comprise a material such as terbium-doped gadolinium oxysulfate ($Gd_2O_2S_2$:Tb), available from USR Optronix, Inc. of Hackettstown, New Jersey. Those of ordinary skill in the art will recognize that other scintillating phosphors, scintillating crystals, and other materials or devices which are

responsive in the x-ray spectrum may also be used in the present invention and are to be considered as x-ray marker materials within the meaning of that phrase as used herein.

Referring to FIG. 3, in an actual embodiment fabricated according to the teachings of the present invention, terbium doped gadolinium oxysulfate phosphor material in a finely ground powder form was both physically mounted and optically coupled to the distal 28 end of optical fiber 24 using an epoxy 30, such as QUIK-STIK, available from GC Electronics of Rockford, Illinois. The epoxy 30 was used to adhere the x-ray marker material 26 to the optical fiber 24 by placing a small amount of the epoxy 30 at the distal end of optical fiber 24 and then dipping the distal end 28 of optical fiber 24 into a finely divided phosphor powder. Similar techniques may be employed to affix a scintillating crystal to the distal end 28 of optical fiber 24. Those of ordinary skill in the art will recognize that the epoxy 30 must be compatible with the phosphor material and must be optically clear at the phosphor emission wavelength. In addition, such skilled persons will recognize that other methods for optically coupling the marker material to the optical fiber, such as employment of a lens, are equivalent and fall within the scope of the present invention.

A photodetector 32 is coupled to the proximate end 34 of optical fiber 24. In an actual embodiment fabricated according to the present invention, the proximate end 34 of optical fiber 24 was coupled to the light-sensitive window of an RCA XT-2020 photomultiplier tube using a high viscosity clear silicone oil, such as available from Dow Corning Corporation of Midland, Michigan.

As will be appreciated by those of ordinary skill in the art, an electrical signal will be generated in photodetector 32 when the catheter 10 of the present invention is exposed to x-ray radiation. Catheter 10 of the present invention is therefore highly useful when employed in applications with digital scanning beam x-ray apparatus, since the x-ray emission is in the form of discrete pixels, enabling location of the catheter's position with a high degree of accuracy.

Those of ordinary skill in the art will appreciate that, although the catheter 10 of FIGS. 1-3 is shown employing a single optically-coupled x-ray marker 26, catheters having a plurality of such optically coupled x-ray markers may be fabricated according to the principles of the present invention. The number of such markers employed in any actual embodiment of the catheter of the present invention will depend solely on the application for which the particular catheter is designed. Specific illustrative examples are disclosed herein.

As those of ordinary skill in the art will also recognize, the present invention may be employed in a wide variety of both steerable and non-steerable catheters for various applications. Without limitation, such catheters and applications will include multi-electrode catheters employed in electrophysiology, and catheters for ablation of cardiac arrhythmia, coronary atherocatheters, etc. The present invention will also be usefully employed, for example, in angioplasty balloon catheters, and in laparoscopy equipment. Such catheters now employ bands of radio-opaque material such as metal, so that they may be located by x-ray techniques during performance of angioplasty procedures. Those of ordinary skill in the art will doubtless be able to envision other applications for the present invention.

Referring now to FIGS. 4a-4c, certain exemplary catheters employing the present invention will be disclosed. Referring first to FIG. 4a, a multi-electrode electrophysiology catheter 40 for use in measuring intracardiac action potentials incorporates the present invention and is shown diagrammatically. An example of such a Commercial electrophysiology catheter of this type is Steerocath Model No. 2037 available from EP Technologies, Inc. of Mountain View, California . For convenience, features of the catheter 40 which are the same as features of catheter 10 of FIGS. 1-3 are identified by the same reference numerals. Thus, catheter 40 is shown to include a plurality of lumens 18, 20, and 22. An optical fiber 24 is disposed in lumen 18 of catheter 10. An x-ray marker material 26 is affixed to a distal end 28 of the optical fiber 24.

A plurality of conductive electrodes 42, 44, 46, and 48 are disposed in spaced-apart relationship near the distal end 14 of catheter 40. Electrodes 42, 44, 46, and 48 are individually electrically coupled to conductors 50, 52, 54, and 56, respectively. Conductors 50, 52, 54, and 56 are disposed in lumen 20 and emerge from its orifice at the proximate end 16 of catheter 40 and may be suitably connected to an electrophysiology recording and analysis system as is known in the art. As shown in FIG. 4a, a photodetector 32 is coupled to the proximate end 34 of optical fiber 24.

Referring now to FIG. 4b, a diagram of a balloon angioplasty catheter 60 employing the present invention is presented. For convenience, features of the angioplasty catheter 60 which are the same as features of catheter 10 of FIGS. 1-3 are identified by the same reference numerals. Thus, angioplasty catheter 60

comprises an elongated body 12 having a distal end 14 adapted to be inserted into a bodily cavity, vessel, tract, or the like and a proximate end 16 available to a person performing a medical procedure.

As will be recognized by persons of ordinary skill in the art, angioplasty catheter 60 includes an inflatable balloon 62 disposed near its distal end 14 which is used as is known in the art. Balloon 62 may be inflated from a lumen 64 with which it communicates. Angioplasty catheter 60 includes a central guidewire lumen 66 through which a guidewire is threaded as is known in the art.

Angioplasty catheter 60 according to the present invention has advantages over prior art angioplasty catheters because it incorporates a plurality of x-ray markers as taught by the present invention. The embodiment illustrated in FIG. 4b shows three such x-ray markers 26a, 26b, and 26c, but those of ordinary skill in the art will recognize that an arbitrary number of markers could be employed if needed.

In the particular example of FIG. 4b, x-ray marker 26a is disposed near the distal side of the balloon and x-ray marker 26b is disposed near the proximate side of the balloon. In addition, x-ray marker 26c is disposed further down the body 12 of the catheter towards its proximate end 16. X-ray markers 26a, 26b, and 26c are optically coupled to first ends of optical fibers 24a, 24b, and 24c, respectively. Optical fibers 24a, 24b, and 24c are shown disposed in individual lumens 18a, 18b, and 18c, although those of ordinary skill in the art will recognize that they might all be disposed in a single lumen if design considerations warranted such placement.

Optical fibers 24a, 24b, and 24c are connected at their second ends to photodetectors 32a, 32b, and 32c. Those of ordinary skill in the art will recognize that the present invention represents a significant advantage over prior art catheters in which x-ray opaque bands are physically attached to selected positions of the catheter. The catheter of the present invention provides the advantage that the positions of the individual x-ray markers (and thus the position of balloon 62) may be uniquely and accurately determined due to their individual coupling to photodetectors 32a, 32b, and 32c. The present invention is easily interfaced to the widely used digital computer video equipment employed with modern x-ray systems so that, when used in conjunction with a scanning x-ray system, the positions of the x-ray markers may be indicated, for example, by blinking cursors, etc., avoiding the ambiguity which is characteristic of interpretation of x-ray displays to locate prior-art catheters.

Referring now to FIG. 4c, a diagram of an atherocatheter employing the present invention is presented. For convenience, features of the catheter 40 which are the same as features of catheter 10 of FIGS. 1-3 are identified by the same reference numerals. Thus, atherocatheter 80 comprises an elongated body 12 having a distal end 14 adapted to be inserted into a bodily cavity, vessel, tract, or the like and a proximate end 16 available to a person performing a medical procedure.

A central guidewire lumen 82 runs through the body of atherocatheter 80 from distal end 14 to proximate end 16 as is known in the art. A tapered coil spring 84 is typically internally disposed at the distal end 14 of atherocatheter 80 and functions to provide a stiff tapered end for the catheter in order to stretch the vessel

in which it is placed. A rotating cutting section 86 comprises a cylindrical member axially disposed in the catheter body behind the tapered distal end 14. A cutting blade 88 is slidably mounted in rotating cutting section 86. Rotating cutting section 86 is coupled to a shaft 90 which runs through a lumen 92 and may be coupled to a motor for rotation. These elements and their relationship to one another are well known in the prior art.

Atherocatheter 80 according to the present invention has advantages over prior art atherocatheters because it incorporates a plurality of x-ray markers as taught by the present invention. The embodiment illustrated in FIG. 4c shows three such x-ray markers 26a, 26b, and 26c, but those of ordinary skill in the art will recognize that an arbitrary number of markers could be employed if needed.

In the particular example of the atherocatheter of FIG. 4c, x-ray marker 26a is disposed near the distal side of the rotating cutting section 86 and x-ray marker 26b is disposed near the proximate side of the rotating cutting section 86. In addition, x-ray marker 26c is disposed further down the body 12 of the catheter towards its proximate end 16. X-ray markers 26a, 26b, and 26c are optically coupled to first ends of optical fibers 24a, 24b, and 24c, respectively. Optical fibers 24a, 24b, and 24c are shown disposed in individual lumens 18a, 18b, and 18c, although those of ordinary skill in the art will recognize that they might all be disposed in a single lumen if design considerations warranted such placement.

Optical fibers 24a, 24b, and 24c are connected at their second ends to photodetectors 32a, 32b, and 32c. Those of ordinary skill in the art will recognize that the present invention represents a significant advantage over prior art

catheters in which x-ray opaque bands are physically attached to selected positions of the catheter. The catheter of the present invention provides the advantage that the positions of the individual x-ray markers (and thus of rotating cutting section 86) may be uniquely and accurately determined due to their individual coupling to photodetectors 32a, 32b, and 32c. As in the embodiment of FIG. 4b, the positions of the x-ray markers in atherocatheter 80 of FIG. 4c may be indicated, for example, by blinking cursors, etc., avoiding the ambiguity which is characteristic of interpretation of x-ray displays to locate prior-art catheters.

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In the case of the atherocatheter, it is important to know which way the opening for the cutting blade is facing. This can be readily determined according to the present invention by partially shielding the x-ray marker material 26, for example, on three sides, leaving only approximately 90 degrees of rotation open to radiation. If more than one marker is shielded and the openings are oriented in different directions, an accurate assessment of catheter rotational orientation may be made.

This aspect of the present invention is illustrated in FIG. 4d, which is a top view of a plurality of x-ray markers according to the present invention. Although four x-ray markers are depicted in FIG. 4d, those of ordinary skill in the art will recognize that other numbers may be employed to affect the resolution with which the rotational position of the catheter may be determined.

Referring now to FIG. 4d, x-ray markers 26a, 26b, 26c, and 26d are disposed in a shielding member 90, which is illustrated in cross section as generally cross shaped. Shielding member 90 is fabricated from a material which

will block x-ray radiation having intensities encountered in the environments within which the catheter employing it will be used. In the typical medical x-ray environment, shield member 90 may comprise, for example, tungsten having a thickness of about 0.025 cm (0.010 in.). It will be possible to utilize other materials and thicknesses because of the ability to compare the outputs of different photodetectors.

Each of x-ray markers 26a, 26b, 26c, and 26d is separately connected to an optical fiber and a photodetector (not shown). In the configuration shown, each of the x-ray markers will be able to determine the rotational position of the catheter in which they are disposed to about a 90° resolution.

Those of ordinary skill in the art will recognize that the top view comprising FIG. 4 does not indicate whether x-ray markers 26a, 26b, 26c, and 26d are disposed at the same point along the length of the catheter in which they are placed. This does not matter and will be a matter of design choice, subject of course to the inaccuracy which would result from twisting of the catheter if they are disposed at different positions along the length of the catheter.

The particular applications and examples disclosed herein are merely illustrative and those of ordinary skill in the art will be readily able to envision other applications for which the present invention is suited. It is intended that all such applications fall within the scope of the present invention.

Referring to FIGS. 5 and 6, illustrative uses of catheter 10 of the present invention are shown. Referring first to FIG. 5, a digital scanning beam x-ray system

100 is shown employed with catheters 10a and 10b shown disposed in a volume 102. Those of ordinary skill in the art will readily recognize that volume 102 could be, for example, a patient into which catheters 10a and 10b have been inserted. Photodetectors 32a and 32b are coupled to the proximate ends of the optical fibers inside of catheters 10a and 10b respectively. Two catheters 10a and 10b, and their associated photodetectors 32a and 32b are shown for purposes of illustration, but those of ordinary skill in the art will recognize that any number of catheters and photodetectors may be employed according to the principles of the present invention.

In the digital scanning beam x-ray system 40 shown in FIG. 5, a scanning X-ray source emits radiation in the x-ray spectrum in a conventional manner using a scan pattern in the x-ray tube 104 as is known in the art. A digital scan controller 106 controls the position of the beam spot on the face of the x-ray tube 104 as is well known in the art. A grid 108 is positioned between the x-ray source 104, and an x-ray detector 110. The grid 108 ensures that x-ray emissions from selected pixel positions of the scanned x-ray tube 104 are directed to a focal point on x-ray detector 110 located behind the volume 102. The x-ray emissions detected by the detector 110 are used to generate a signal which is then sent to an image processor (not shown) for analysis.

As the emissions travel their various paths from the grid 108 to the detector 110, some of the emissions are intercepted by and irradiate the phosphor material disposed on the distal ends of optical fibers 24a and 24b in catheters 10a and 10b, respectively. The phosphor material responds by emitting light, which is directed down the optical fibers 24a and 24b to photodetectors 32a and 32b which convert

the light to an electrical signal. Those of ordinary skill in the art will recognize that the signal output from the photodetectors 32a and 32b will be at a maximum when the center of the cone of radiation which is allowed to pass through grid 108 is centered on the phosphor material each catheter.

Control unit 112 is supplied with the x and y addresses from the scan controller 106 and with the output signals from photodetectors 32a and 32b. Control unit 112, which may be a well-known comparator and a well-known coincidence detector, correlates the output signals from photodetectors 32a and 32b with the scan address information from scan controller 106. This information may then be processed and thus may be used to determine the positions of the phosphor material in catheters 10a and 10b, and hence is an accurate indicator of the positions of the ends of the catheters themselves. It will be appreciated that the catheter positions can be located to within one or two pixel positions using the instant invention.

Referring now to FIG. 6, it will be appreciated by those of ordinary skill in the art that two x-ray tubes 104a and 104b, employing independent scan controllers 106a and 106b, grids 108a and 108b, and x-ray detectors 110a and 110b may be used in combination with catheters 10a, 10b, and 10c, photodetectors 30a and 30b, and control unit 112 to accurately locate the positions of the catheters 10a, 10b, and 10c in three dimensions by employing two of the catheters as reference catheters and a third as a mapping catheter whose position with respect to the other two catheters may be determined.

When used as described herein, the above-described embodiment of the

present invention answers the long felt need for anatomical markers during cardiac diagnostic and treatment procedures. For various reasons known to those skilled in the art, the alternative imaging modalities of MRI, CT, and ultrasound are not suitable for these procedures. However, the use of prior-art methods employing x-ray fluoroscopes for imaging has the serious disadvantage of not being able to distinguish anatomical detail inside the heart. The physician uses the shadows generated, his or her intimate knowledge of the anatomy, the characteristic movement of the image and catheters caused by the cardiac cycle and the respiratory cycle, and for fine positioning, the electrocardiogram.

Since typical reference positions for electrocardiograms are the high right atria, the bundle of His, the right ventricle, and the coronary sinus, there is an opportunity to have three points located in the x-ray image at any point in the cardiac cycle. These three points can precisely locate the coordinates of the ablation catheter. The physician can then map an area with the catheter and correlate its position with the electrocardiograms. He can then return to the same spot after leaving it and can measure bounce or other movement, he can also measure internal dimensions of the heart mapping points, determine wall thicknesses, build 3D images from the data and overlay cardiac action potentials. In addition, in a subsequent procedure the same locations may be found from overlaying the maps of anatomy and cardiac potentials.

The initial work performed in this invention was to analyze the images from a biplane x-ray system when it was gated to the cardiac cycle. In some cases this positioning using image analysis is adequate but the precision can be greatly improved if a sensor is included in the catheter which is smaller than the smallest pixel in the output. With conventional image intensifier technology, such a point

sensor would not be useful since the entire field of view is irradiated simultaneously. However, in a scanning beam digital x-ray system, the beam is divided such that each pixel is separated in time and therefore the location of the sensor in each individual catheter can be uniquely identified with a pixel. By utilizing a stereo or biplane scanning beam system, the sensor can be located in three dimensions provided that the two beams are synchronized. In cardiac applications, the cardiac cycle must be gated.

The advantage of the above described medical catheter embodiment of the invention is that it permits existing catheters inside the patient to now also function as anatomical markers, significantly reducing the time to map and ablate. Additional advantages are more detailed mapping of the cardiac substrate, correlation of the intercardiac electrodes with anatomical location, display in three dimensions if desired of the intercardiac electrodes on an image of the heart, and comparison of electrograms from studies done at different times by overlaying.

While embodiments and applications of this invention have been shown and described, it would be apparent to those skilled in the art that many more modifications than mentioned above are possible without departing from the inventive concepts herein. The invention, therefore, is not to be restricted except in the spirit of the appended claims.

What is Claimed is:

1. An x-ray sensor for determining position of an associated object in a field of view covered by a scanning x-ray beam comprising an x-ray marker optically coupled to an optical fiber.

2. The x-ray sensor of claim 1 further including x-ray shielding means for selectively allowing x-ray radiation to reach said x-ray marker only from selected directions.

3. An x-ray sensing catheter comprising:

an elongated body formed from a pliant material and having a distal end and a proximate end, said elongated body including at least one lumen axially disposed therein;

an optical fiber disposed in said at least one lumen, said optical fiber having a distal end disposed at a selected location with respect to said distal end of said elongated body and having a proximate end associated with said proximate end of said elongated body ; and

an x-ray marker affixed to said distal end of said optical fiber.

4. The x-ray sensing catheter of claim 3 further including x-ray shielding means, partially enveloping said x-ray marker for selectively allowing x-ray radiation to reach said x-ray marker only from selected directions.

5. The x-ray sensing catheter of claim 4 wherein said selected directions are defined by a conic section having an apex at said x-ray marker and having an axis perpendicular to said elongated body.

6. The x-ray sensing catheter of claim 3 in combination with a photodetector coupled to said proximate end of said optical fiber.

7. A catheter comprising:

an elongated body formed from a pliant material and having a distal end and a proximate end, said elongated body including at a plurality of lumens axially disposed therein;

a plurality of x-ray markers, each of said x-ray markers disposed in one of said lumens at selected positions along said elongated body;

an plurality of optical fibers, each optical fiber disposed in one of said lumens and having a distal end optically coupled to a different one of said x-ray markers and a proximate end associated with said proximate end of said elongated body;

x-ray shielding means associated with each of said x-ray markers, each x-ray shielding means partially enveloping its x-ray marker for selectively allowing x-ray radiation to reach said x-ray marker only from selected directions.

8. The x-ray sensing catheter of claim 7 wherein said selected directions of each of said x-ray shielding means are spaced equidistantly around a circle perpendicular to an axis parallel to said elongated body so as to provide an indication of the rotational position of said catheter.

9. A catheter comprising:

an elongated body formed from a pliant material and having a distal end and a proximate end, said elongated body including at least one lumen axially

disposed therein;

an optical fiber disposed in said at least one lumen of said catheter, said optical fiber having a distal end disposed at a selected location with respect to said distal end of said elongated body and having a proximate end associated with said proximate end of said elongated body;

an x-ray marker affixed to said distal end of said optical fiber;

at least one conductive electrode disposed on an outer surface of said catheter near said distal end thereof; and

a conductor electrically connected to said at least one electrode, said conductor running through said at least one lumen of said catheter and accessible at said proximate end of said catheter for electrical connection thereto.

10. A catheter comprising:

an elongated body formed from a pliant material and having a distal end and a proximate end, said elongated body including at a plurality of lumens axially disposed therein;

a plurality of x-ray markers, each of said x-ray markers disposed in one of said lumens at selected positions along said elongated body;

a plurality of optical fibers, each optical fiber disposed in one of said lumens and having a distal end optically coupled to a different one of said x-ray markers and a proximate end associated with said proximate end of said elongated body;

at least one conductive electrode disposed on an outer surface of said catheter near said distal end thereof; and

a conductor electrically connected to said at least one electrode, said conductor running through said at least one lumen of said catheter and accessible

at said proximate end of said catheter for electrical connection thereto.

AMENDED CLAIMS

[received by the International Bureau on 28 June 1994 (28.06.94) ; original claims 1-10 replaced by amended claims 1-14 (5 pages)]

1. An x-ray sensor for determining the position of an associated object in a field of view covered by a scanning x-ray beam, comprising an x-ray marker capable of generating optical signals in response to exposure to x-ray radiation, said x-ray marker optically coupled to an optical fiber for transmitting said optical signals.

2. An x-ray sensor for determining the position of an associated object in a field of view covered by a scanning x-ray beam comprising

an x-ray marker optically coupled to an optical fiber; and

x-ray shielding means for selectively allowing x-ray radiation to reach said x-ray marker only from selected directions.

3. An x-ray sensor catheter as in claims 1 or 2, further comprising a photodetector coupled to said optical fiber and responsive to said optical signals.

4. An x-ray sensing catheter comprising

an elongated body formed from a pliant material, said elongated body having a distal end, a proximate end and at least one lumen axially disposed therein;

an optical fiber disposed in said at least one lumen, said optical fiber having a distal end disposed at a selected location with respect to said distal end of said elongated body and having a proximate end associated with said proximate end of said elongated body; and

an x-ray marker capable of generating optical signals in response to exposure to x-ray radiation, said x-ray marker affixed to said distal end of said optical fiber.

5. An x-ray sensing catheter comprising

an elongated body formed from a pliant material, said elongated body having a distal end, a proximate end and at least one lumen axially disposed therein;

an optical fiber disposed in said at least one lumen, said optical fiber having a distal end disposed at a selected location with respect to said distal end of said elongated body and having a proximate end associated with said proximate end of said elongated body;

an x-ray marker affixed to said distal end of said optical fiber; and

x-ray shielding means for selectively allowing x-ray radiation to reach said x-ray marker only from selected directions.

6. An x-ray sensing catheter as in claim 5, wherein said x-ray shielding means partially envelops said x-ray marker.

7. An x-ray sensing catheter as in claims 5 or 6, wherein said selected directions are defined by a conic section having an apex at said x-ray marker and having an axis perpendicular to said elongated body.

8. An x-ray sensing catheter as in any of claims 4, 5, 6, or 7, wherein said x-ray marker is optically coupled to said distal end of said optical fiber so that said optical signals may be transmitted through said optical fiber; and comprising a photodetector coupled to said proximate end of said optical fiber and responsive to said optical signals.

9. An x-ray sensing catheter as in any of claims 4, 5, 6, 7, or 8, further comprising

at least one conductive electrode disposed on an outer surface of said elongated body near said distal end thereof; and

a conductor electrically connected to said at least one electrode, said conductor running through said at least one lumen of said elongated body and accessible at said proximate end of said elongated body for electrical connection thereto.

10. A catheter comprising

an elongated body formed from a pliant material having a distal end, a proximate end and a plurality of lumens axially disposed therein;

a plurality of x-ray markers, each of said x-ray markers disposed in one of said lumens at selected positions along said elongated body;

a plurality of optical fibers, each of said optical fibers disposed in one of said lumens and having a distal end optically coupled to a different one of said x-ray markers and a proximate end associated with said proximate end of said elongated body;

x-ray shielding means associated with each of said x-ray markers, each x-ray shielding means partially enveloping its associated x-ray marker for selectively allowing x-ray radiation to reach said x-ray marker only from selected directions.

11. A catheter as in claim 10, wherein said selected directions of each of said x-ray shielding means are spaced around a closed loop perpendicular to an axis parallel to said elongated body so as to provide an indication of the rotational position of the catheter.

12. A catheter comprising

an elongated body formed from a pliant material having a distal end, a proximate end and at least one lumen axially disposed therein;

an optical fiber disposed in said at least one lumen of said elongated body, said optical fiber having a distal end disposed at a selected location with respect to said distal end of said

elongated body and having a proximate end associated with said proximate end of said elongated body;

an x-ray marker affixed to said distal end of said optical fiber;

at least one conductive electrode disposed on an outer surface of said elongated body near said distal end thereof; and

a conductor electrically connected to said at least one electrode, said conductor running through said at least one lumen of said elongated body and accessible at said proximate end of said elongated body for electrical connection thereto.

13. An catheter as in claim 12, wherein said x-ray marker is optically coupled to said distal end of said optical fiber so that said optical signals may be transmitted through said optical fiber; and comprising a photodetector coupled to said proximate end of said optical fiber and responsive to said optical signals.

14. A catheter comprising

an elongated body formed from a pliant material having a distal end, a proximate end and a plurality of lumens axially disposed therein;

a plurality of x-ray markers, each of said x-ray markers disposed in one of said lumens at selected positions along said elongated body;

a plurality of optical fibers, each optical fiber disposed in one of said lumens and having a distal end optically coupled to a different one of said x-ray markers and a proximate end associated with said proximate end of said elongated body;

at least one conductive electrode disposed on an outer surface of said elongated body near said distal end thereof; and

a conductor electrically connected to said at least one electrode, said conductor running through said at least one lumen of said elongated body and accessible at said proximate end of said elongated body for electrical connection thereto.

STATEMENT UNDER ARTICLE 19

US 4,945,894 (Kawashima) merely shows an x-ray non-transmissive material attached to an end of an endoscope, so that the position of the endoscope can be confirmed by an external x-ray device. Kawashima's material is not optically reactive, and does not transmit any signal in response to x-rays. Rather, Kawashima's material is completely passive.

Claims 1 and 4 (formerly claim 3) specifically recite x-ray markers that are optically reactive, unlike the marker in Kawashima. Moreover, the whole point to Kawashima's marker is to place a non-transmissive structure at the end of the catheter so it will show up on the x-ray screen. Kawashima does not show or suggest coupling the marker to an optical fiber to carry a signal out of the catheter for any purpose.

Since Kawashima does not show a marker which produced an optical signal in response to x-ray radiation, it would not be possible to combine Kawashima and US 3,992,631 (Harte) to arrive at subject matter recited in claim 8 (formerly claim 6). Moreover, claim 8 has been amended to depend from any one of claims 4 (formerly claim 3), 5, 6, or 7. Such an x-ray marker is not shown in either Kawashima or Harte. Provision of such an x-ray marker therefore clearly involves an inventive step.

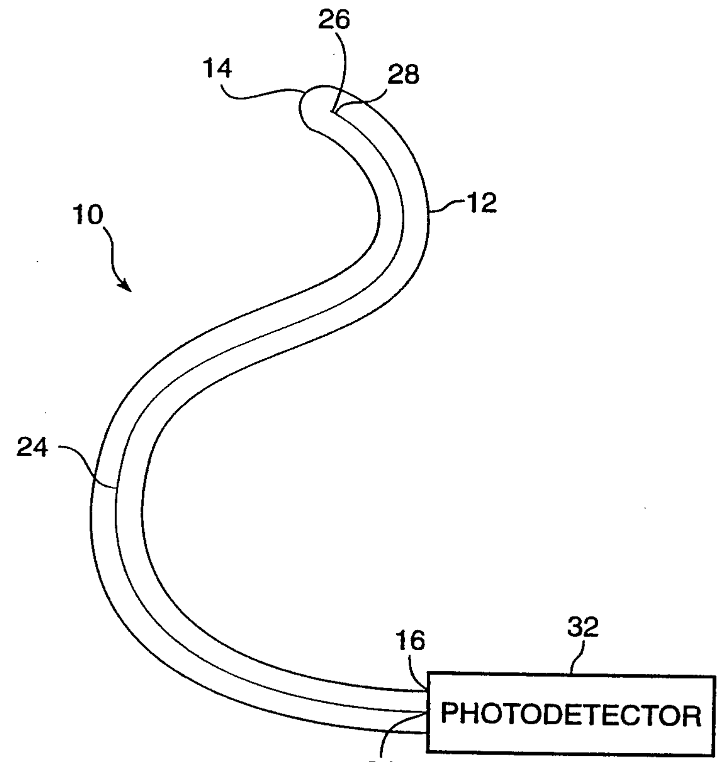


FIG. 1

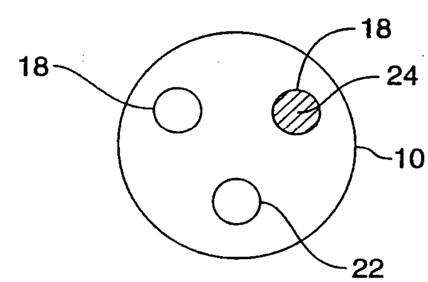


FIG. 2

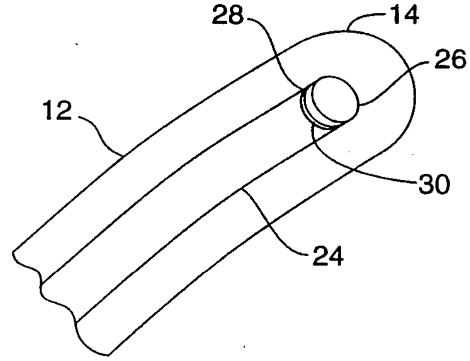


FIG. 3

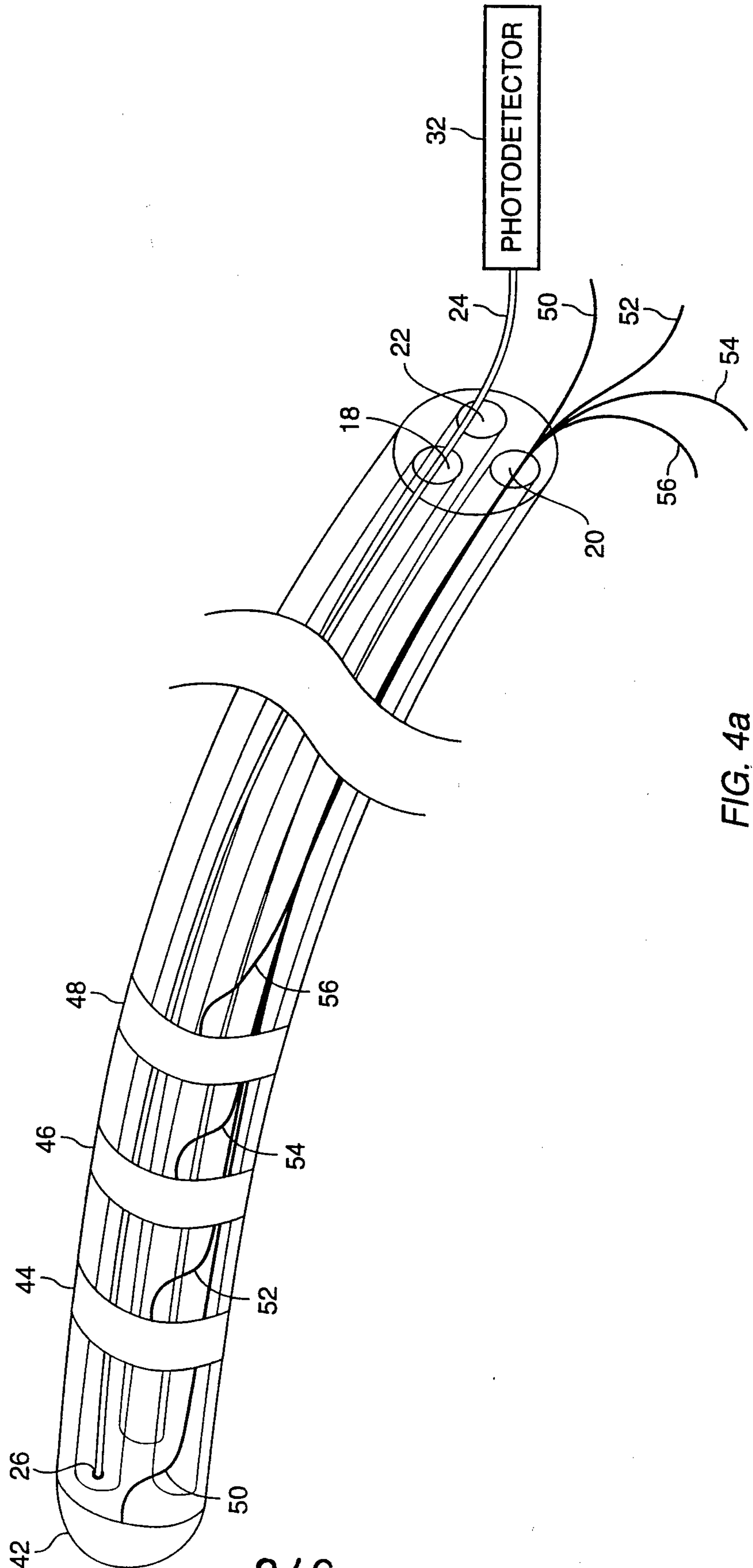
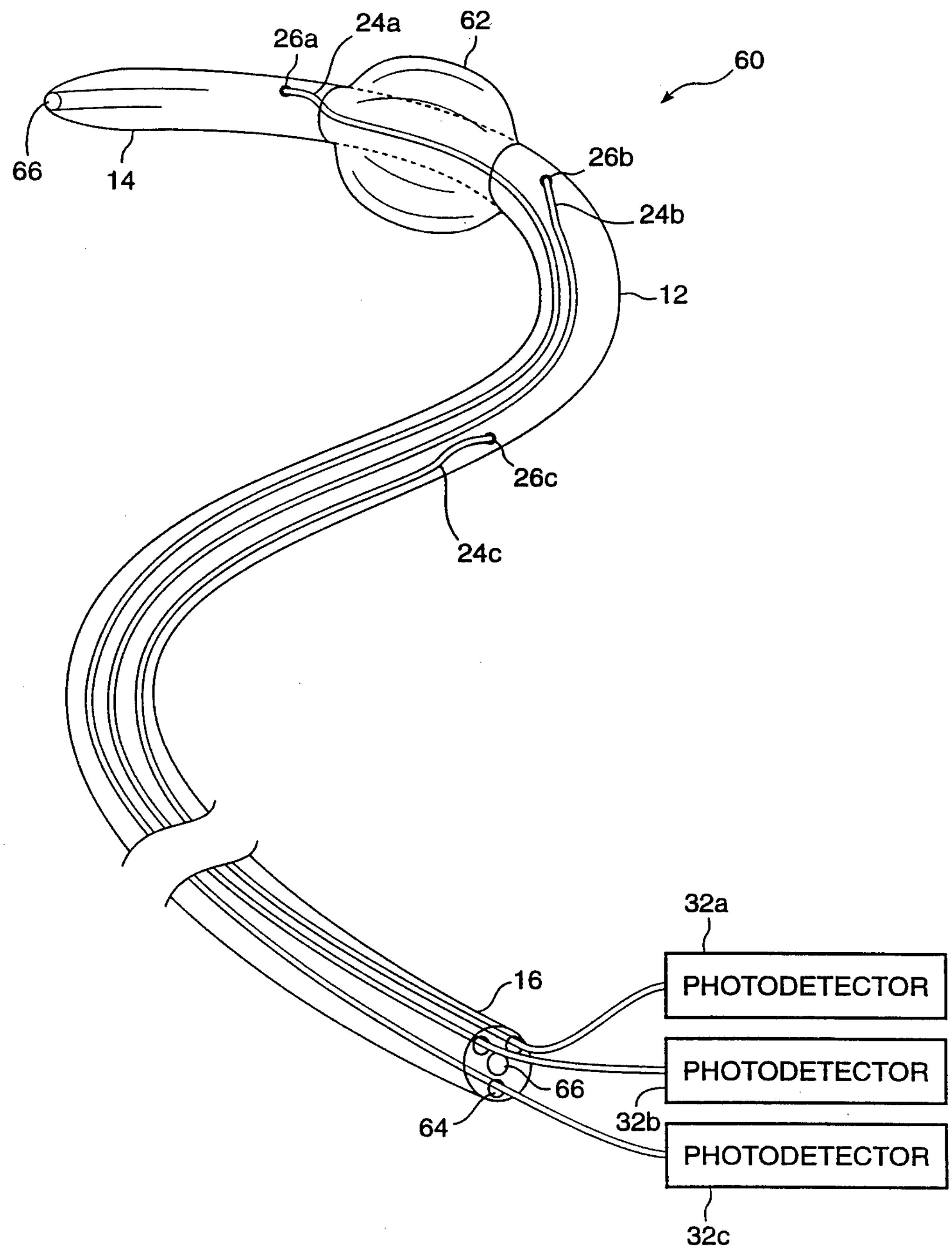


FIG. 4a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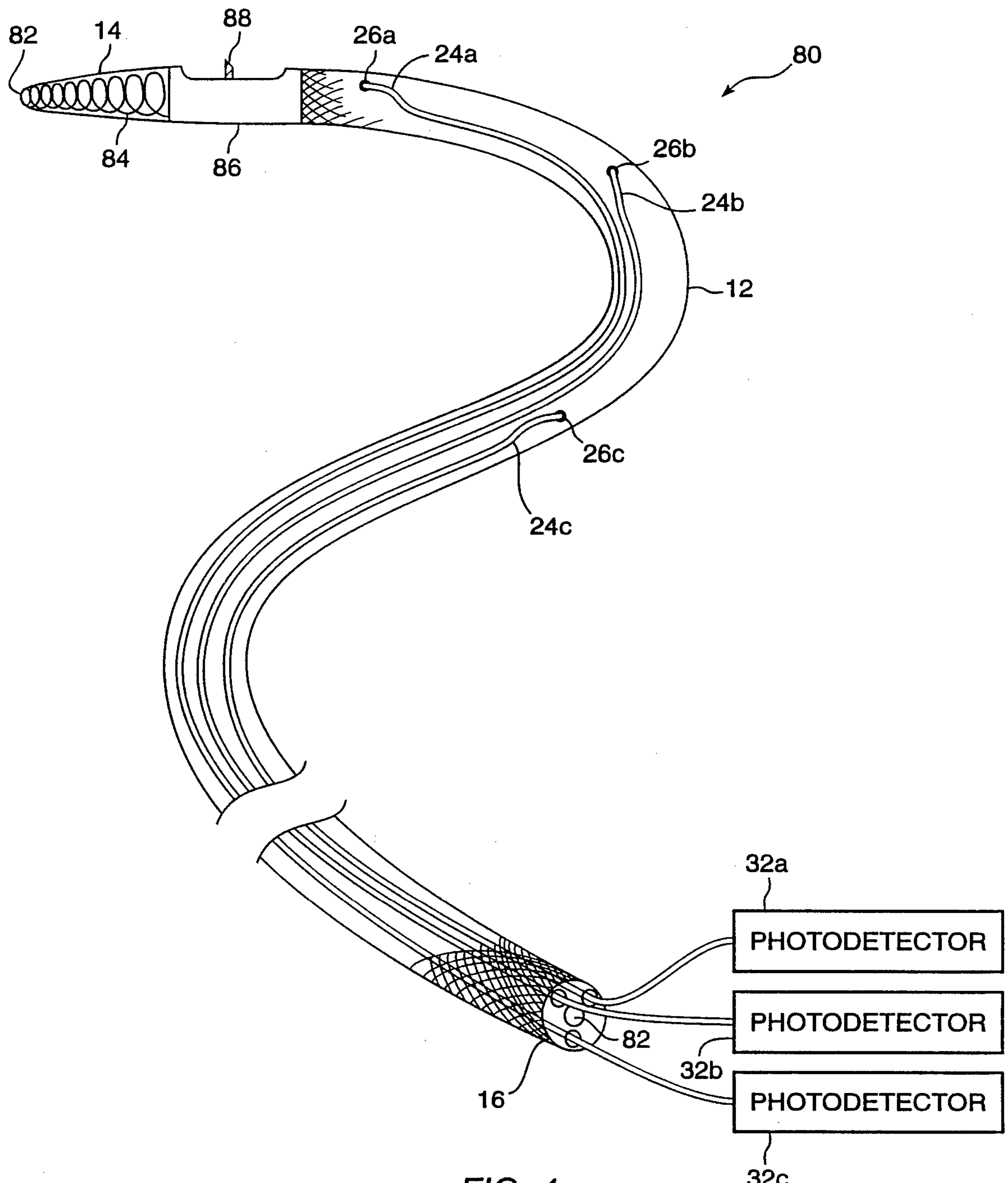
24a
62
60
66
14
26b
24b
12
26c
24c
32a
16
PHOTODETECTOR
PHOTODETECTOR
66
64
32b
PHOTODETECTOR
32c

FIG. 4b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86
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24b
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26c
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32a
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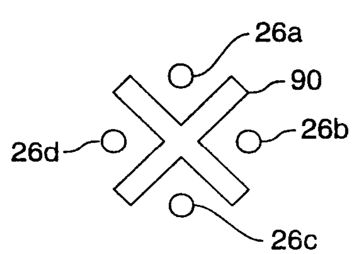
82
32b
PHOTODETECTOR
16
32c

FIG. 4c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26d
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26c

FIG. 4d

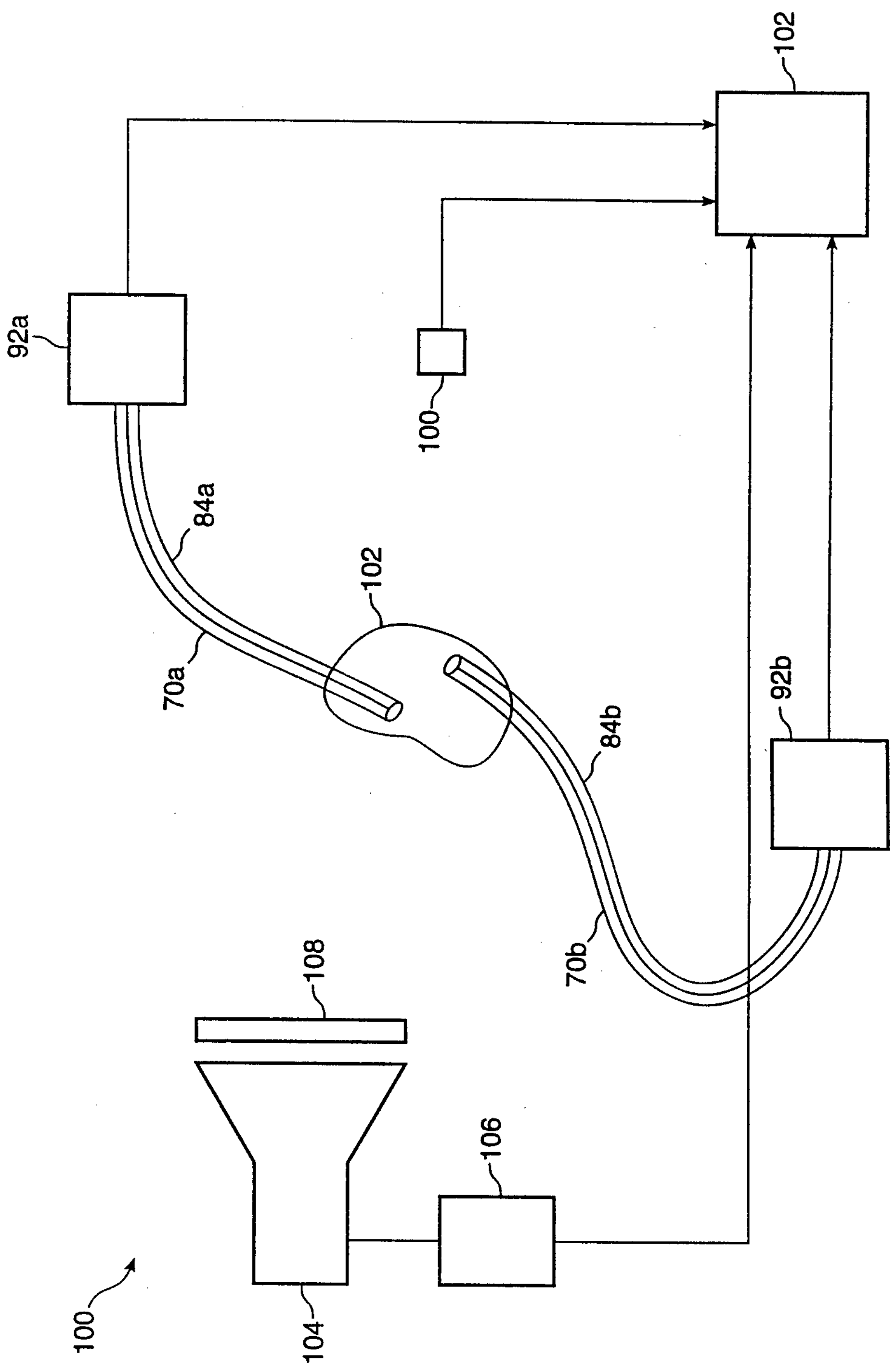
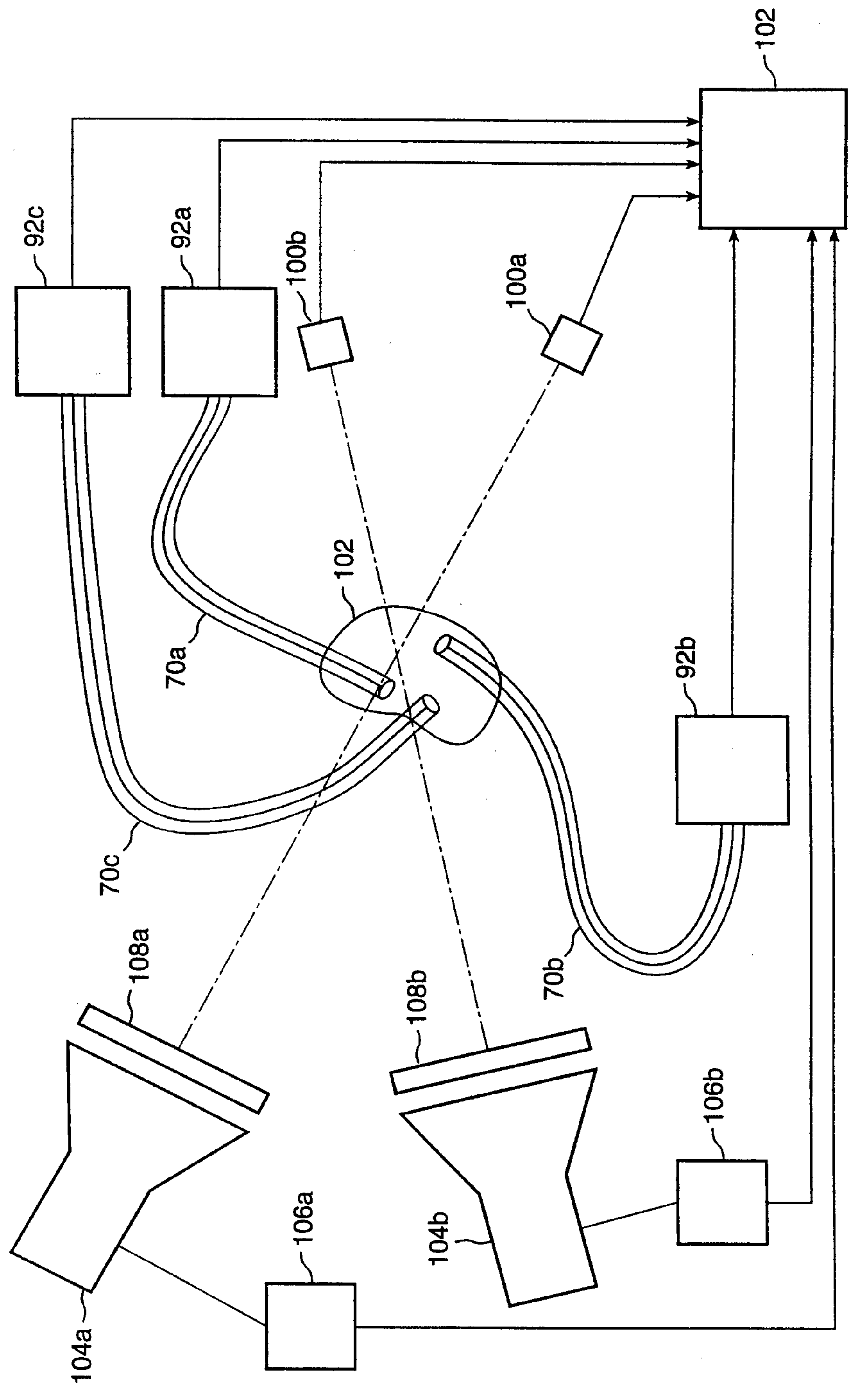


FIG. 5



102
92c
92a
100b
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70c
92b
70b
108a
108b
106b
106a
104b
104a

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/00957

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 6/00
US CL :128/656
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/4, 6, 7, 653.1, 654, 656, 658, 772; 250/302, 491.1, 515.1; 378/163.20; 606/13-16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,945,894 (Kawashima) 07 August 1990, see col. 4, lines 12-56.	1,3 ----- 6
Y	US, A, 3,992,631 (Harte) 16 November 1976, see entire document.	6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:
"A"	document defining the general state of the art which is not considered to be part of particular relevance
"E"	earlier document published on or after the international filing date
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O"	document referring to an oral disclosure, use, exhibition or other means
"P"	document published prior to the international filing date but later than the priority date claimed
"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&"	document member of the same patent family

Date of the actual completion of the international search 02 MARCH 1994	Date of mailing of the international search report 18 APR 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer BRIAN CASLER
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0858

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